

Amendments to the Drawings:

The attached sheet of drawings includes changes to FIGURE 1 and replaces the original sheet including FIGURE 1. In the attached replacement sheet, the labels that were previously included in that figure have been deleted and replaced with appropriate reference numerals in accordance with the specification of the present application.

Attachment: Replacement Sheet

REMARKS

By this amendment, claims 79-82 and 92 have been amended, claims 94 and 95 have been added, and claims 83-85 have been cancelled without prejudice. Claims 47-78 stand withdrawn from consideration and thus claims 79-82 and 86-95 are currently under examination in the present application. For the reasons set forth below, Applicants submit that the present amendments and arguments place this application in condition for immediate allowance.

As an initial matter, Applicants respectfully submit that the addition of claims 94 and 95 and the amendments to the drawings included with this response are proper and should be entered as no new matter has been added by these amendments. In particular, claims 94 and 95 have merely been added to further recite a particular arrangement of the claimed electrodes and a range of depths at which the electrodes are capable of measuring impedance. Support for these amendments can be found, for example, on pages 10-11 of the present application, as filed. Similarly, with respect to the amendments to the drawings included with this response, Figure 1 has simply been amended to replace the labels previously included in that Figure with appropriate reference numerals, which can also be found, for example, on pages 10-11 of the application, as filed. Accordingly, no new matter has been added by the present amendments and Applicants further respectfully submit that it is believed that no additional corrections to the drawings or specification are required at this time.

In the Office Action dated March 31, 2009, the Examiner first made several minor objections to claims 79-93 under 35 U.S.C. §112, second paragraph as being indefinite.

In particular, the Examiner asserted that the reference to withdrawn claim 47 in claim 79 rendered the metes and bounds of claim 79 unclear. Further, the Examiner also asserted that insufficient antecedent basis existed for several of the terms in claim 79. Without addressing the merits of these assertions, by the present amendments, claim 79 has now been amended to remove the reference to withdrawn claim 47 and to instead recite that the claimed apparatus is also used to for “measuring” blood glucose levels, as recited in withdrawn claim 47. Additionally, by the present amendments, claim 79 has also been amended to correct the antecedent basis issues for the terms in that claim. Accordingly, Applicants respectfully submit that these rejections have been rendered moot by virtue of the present amendments and should be withdrawn.

In the Office Action, the Examiner then rejected claims 79-93 under 35 U.S.C. §101 as being directed toward non-statutory subject matter. Specifically, the Examiner asserted that claims 79 and 92 recited a positive relation to the human body in their recitation of “...electrodes...in electrically conductive contact with the first body tissue...” and “the apparatus...implanted in the body tissue,” respectively. Without addressing the merits of the Examiner’s assertions, these rejections have also been rendered moot by virtue of the present amendments, which amend claims 79 and 92 to refer to the electrodes and apparatus as “being adapted for” contact or implantation, in accordance with the Examiner’s suggestions. As such, Applicants respectfully submit that the Examiner’s rejections under 35 U.S.C. §101, insofar as applied to the claims as amended, should be withdrawn.

In the Office Action, the Examiner next rejected claims 79-85, 88-89, and 91-93 under 35 U.S.C. §102(e) as being anticipated by U.S. Patent Application Publication No. 2003/0130616 (Steil, et al.). In particular, the Examiner asserted that Steil discloses an apparatus for monitoring glucose concentrations that includes a working electrode and a counter electrode, and that these teachings would anticipate the present invention. For the reasons set forth below, Applicants submit that this rejection is respectfully traversed and should be withdrawn.

As reflected in the claims of the present application, as amended, the present invention relates to an apparatus for measuring or monitoring glucose levels in a subject that includes one or more pairs of electrodes for measuring the impedance of an electrical current. Specifically, Applicants have found that by using a pair of electrodes, consisting of an injection electrode and a sensing electrode, electrical current can be injected into a body tissue and then detected such that the impedance of the current can be measured and then correlated with a predetermined relationship between impedance and glucose levels to thereby determine the amount of blood glucose in a subject.

In contrast to the present application, Steil describes a closed loop infusion system that controls the rate that a fluid is infused into the body of a user, and which can monitor the glucose concentration in the body of the user when insulin is being infused by the system. The infusion system described in Steil includes a controller, a delivery system, and a sensor system, which includes a working electrode, a reference electrode, and a counter electrode (see, e.g., para. [0319]). However, there is no teaching or suggestion whatsoever in Steil that only two electrodes could be used for measuring impedance and

determining blood glucose, as is the case in the present application. Instead, Steil clearly teaches that all three electrodes are required to form a circuit which can then be used to measure the observed impedance. Accordingly, it is thus the case that Steil can not be fairly characterized as anticipating the present invention when there is no teaching or suggestion in Steil as to an apparatus that includes only two electrodes.

In this regard, by the present amendments, Applicants have amended claim 79 to further clarify that the one or more pairs of electrodes of the claimed apparatus consist of two electrodes, namely an injection electrode for injection of electrical current into a first body tissue and a sensing electrode that detects the electrical current after it flows through the first body tissue. Furthermore, claims 80-82 have been amended to clarify that these electrodes can be provided as a single pair or multiple pairs of electrodes and then used to inject electrical current into a variety of body tissues, including skin, sub-dermal tissue, or subcutaneous tissue. Support for all of these amendments can be found, for example, on pages 10-11 of the application, as filed.

Accordingly, in light of the foregoing comments and amendments, Applicants respectfully submit that the present invention, as reflected in the claims as amended, is not anticipated by the cited Steil reference and that the claims of the present application are clearly patentable over that reference. Applicants thus submit that the Examiner's rejections on the basis of that reference are respectfully traversed and should be withdrawn.

In the Office Action dated March 31, 2009, the Examiner also made various rejections to claims 86, 87, and 90 under 35 U.S.C. §103(a) as being unpatentable over Steil in view of U.S. Patent Application Publication No. 2004/0182719 (Purvis, et al.), U.S. Patent No. 6,517,482 (Elden, et al.), and/or U.S. Patent Application Publication No. 2002/0049389 (Abreu). In making the rejections, the Examiner asserted that although Steil does not disclose various features of the claimed invention, that it would have been obvious to modify the sensors of Steil to include those various features in light of the teachings of the secondary references.

As described above, however, the present invention relates to an apparatus for measuring or monitoring glucose levels in a subject that includes one or more pairs of electrodes, where each pair of electrodes consists of an injection electrode and a sensing electrode. Steil does not include any teaching or suggestion whatsoever regarding the use of only two electrodes to measure impedance of an electrical current and determine the amount of blood glucose in a subject. Instead, Steil describes the use of three electrodes, namely a working electrode, a reference electrode, and a counter electrode, that must necessarily be used to form a circuit so that impedance may be measured. There is no teaching or suggestion in Steil that the three-electrode format of its apparatus could be altered such that only two electrodes could be used to measure impedance and determine blood glucose levels. Moreover, the cited Purvis, Elden, and Abreu references add nothing further in this regard, and were merely cited by the Examiner for their teachings with respect to amperometers and voltmeters, frequencies of electrical currents, and processors, respectively.

Accordingly, Applicants respectfully submit that the claims of the present application are not rendered obvious by the cited Steil, Purvis, Elden, and Abreu references and, accordingly, Applicants thus submit that the Examiner's rejection is respectfully traversed and should be withdrawn.

In light of the amendments and arguments provided herewith, Applicants submit that the present application overcomes all prior rejections and objections, and has been placed in condition for immediate allowance. Such action is respectfully requested.

Respectfully submitted,



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